

PCT

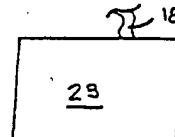
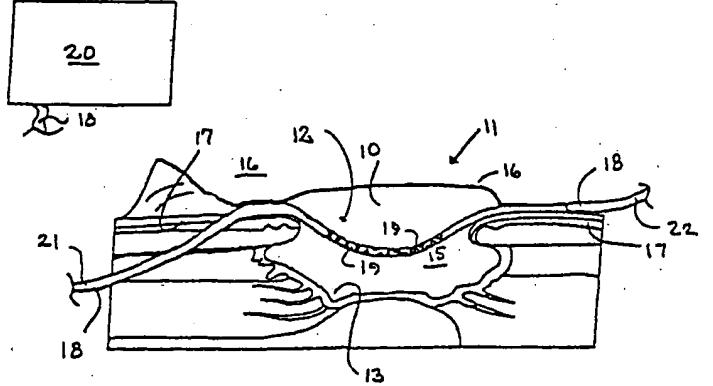
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ :	A2	(11) International Publication Number: WO 00/38755 (43) International Publication Date: 6 July 2000 (06.07.00)
(21) International Application Number: PCT/US99/30702 (22) International Filing Date: 23 December 1999 (23.12.99)		(81) Designated States: AU, CA, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(30) Priority Data: 60/113,732 23 December 1998 (23.12.98) US		Published <i>Without international search report and to be republished upon receipt of that report.</i>
(71) Applicant (for all designated States except US): KCI LICENSING, INC. [US/US]; 8023 Vantage Drive, San Antonio, TX 78230 (US).		
(72) Inventor; and (75) Inventor/Applicant (for US only): RANDOLPH, L., Tab [US/US]; 27917 Bonn Mountain, San Antonio, TX 78260 (US).		
(74) Agents: COLTON, Wayne, J.; Wayne J. Colton, Inc., The Milam Building, Suite 1108, 115 East Travis Street, San Antonio, TX 78205 (US) et al.		

(54) Title: METHOD AND APPARATUS FOR WOUND TREATMENT



(57) Abstract

A wound treatment device comprises a polyurethane or polyether foam pad, adapted for insertion substantially within a wound cavity; a pump for supplying fluid flow to the wound site; and a collection canister for receiving wound fluids drawn from the wound cavity. The foam pad, pump and collection canister are in fluid communication with one another through a single hospital grade hose having a plurality of tiny apertures in the portion that is central to the foam pad. These apertures are adapted to allow fluids from the wound cavity to be drawn into the flow from the pump to the canister according to Bernoulli's theorem.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

METHOD AND APPARATUS FOR WOUND TREATMENT

5

TECHNICAL FIELD:

10 The present invention relates to the treatment of wounds. More particularly, the invention relates to the therapeutic application of a positive fluid flow to a wound site for the promotion of wound healing.

BACKGROUND ART:

15 It is known in the prior art that wound closure requires that the epithelial and subcutaneous tissues adjacent the wound migrate toward the wound. Unfortunately, in the case of large or infected wounds, such as are often the result of chronic disease or pressure sores, spontaneous closure does not take place. In these cases, localized swelling forms near the surface of the wound restricting the flow of blood. As a result of this diminished blood flow the wound is unable to successfully fight bacterial infection. The resulting increased infection in turn causes further restriction of blood flow, which results in further diminished blood flow and so forth, ultimately leading to the necessity for radical intervention. In many cases, the patient requires hospitalization for drug administration and/or surgical relief.

20 The application of continuous negative pressure has been shown to contribute significantly to wound closure. Such applications typically involve the insertion of an open-cell foam pad into a wound region. The pad is then covered with a polymer sheet to seal the

region from atmosphere. Thereafter, negative pressure is applied to the wound site through a tube having one end inserted into the interior of the foam pad and the opposite end attached to a vacuum pump via an interposed chamber for collection of wound fluids. Clinical results demonstrate that such applications of negative pressure promote the migration of epithelial and subcutaneous tissue toward the wound while serving to evacuate wound exudate and reduce bacterial density.

Unfortunately, the application of continuous negative pressure makes difficult the administration of topical disinfectant drugs and control of the local atmospheric content and does little to promote drying of the wound area. It is therefore desired to achieve infection control in a manner that promotes the application of topical disinfectants while allowing the caregiver to adjust the local atmospheric condition, including content and temperature. The removal of wound fluids through continuous negative pressure also suffers the disadvantage of requiring strict infection control. This is most often accomplished through the provision of very expensive hydrophobic filters between the collection canister and vacuum pump and other safety measures. It is therefore desired to eliminate necessity for such expensive apparatus while still providing a safe and effective means for exudate removal.

DISCLOSURE OF THE INVENTION:

In accordance with the foregoing objects, the present invention – a method and apparatus for wound treatment – generally comprises a polyurethane or polyether foam pad, adapted for insertion substantially within a wound cavity; a pump for supplying fluid flow to the wound site; and a collection canister for receiving wound fluids drawn from the wound cavity. The foam pad, pump and collection canister are in fluid communication with one another through a single hospital grade hose having a plurality of tiny apertures in the portion that is central to the foam pad. These apertures are adapted to allow fluids from the wound cavity to be drawn into the flow from the pump to the canister according to Bernoulli's

theorem.

Many other features, objects and advantages of the present invention will be apparent to those of ordinary skill in the relevant arts, especially in light of the foregoing discussions and the following drawings, exemplary detailed description and appended claims.

5

BRIEF DESCRIPTION OF THE DRAWINGS:

Although the scope of the present invention is much broader than any particular embodiment, a detailed description of the preferred embodiment follows together with illustrative figures, wherein like reference numerals refer to like components, and wherein:

10 Figure 1 shows a partial cross section of a known apparatus for application of continuous negative pressure to a wound site; and

Figure 2 shows a partial cross section of a the preferred embodiment of the present invention as applied to a wound site, including in block diagram the pump and collection canister forming a part thereof.

15

BEST MODE FOR CARRYING OUT THE INVENTION:

Although those of ordinary skill in the art will readily recognize many alternative embodiments, especially in light of the illustrations provided herein, this detailed description is exemplary of the preferred embodiment of the present invention, the scope of which is limited only by the claims that may be drawn hereto.

Referring to Figure 1, there is shown a partial cross-sectional view of an open cell polyurethane or polyether foam pad 10 as inserted into a wound site 11 for application of continuous negative pressure as previously known in the art. As detailed in the figure, the foam pad 10 is cut to size so as to pack the foam 10 into the wound cavity 12, making contact 20 with the full surface 13 of the cavity 12. A drainage tube 14, preferably comprising medical grade polyvinyl chloride (PVC), is terminated within the central portion 15 of the foam pad

10 and the pad 10 and tube 14 combination is covered with a surgical drape 16. The drape 16 is preferably adhered firmly to the intact skin 17 peripheral the wound site 11 as well as to the drainage tube 14 in order to provide an air-tight seal around the wound 11. Negative pressure is then applied through the drainage tube 14 utilizing known apparatus not shown
5 here.

Referring now to Figure 2, there is shown a partial cross-sectional view of an open cell polyurethane or polyether foam pad 10 as inserted into a wound site 11 for application of positive pressure according to the teachings of the present invention. While the present invention employs many principles known from the art of negative pressure applications for
10 wound site preparation, material selection and even therapeutic modality, the present invention varies from the known art in several critical areas. First, the present invention is adapted to apply a positive pressure to the wound site 11. As shown in the figure, the PVC tube 18 providing fluid communication both to and from the inserted pad 10 comprises a plurality of tiny apertures 19 in the region 15 central to the pad 10. Positive pressure,
15 preferably generated with a non-oil type clean air delivery pump 20 meeting applicable hospital standards such as UL-544, is delivered to a first end 21 of the tube. By varying the temperature and flow rate of the fluid delivered to the wound site 11 through the tube 18 and provided apertures 19, the caregiver is given the ability to control the drying characteristics of the fluid. Additionally, the caregiver can vary the content of the fluid in order to promote
20 increased healing. For example, the pump 20 may be adapted to deliver pure O₂ for a localized hyperbaric effect or O₃ for ozone treatment and infection controlling drugs may be easily admitted into the flow stream for topical administration to the wound 11.

In addition, the placement of the tiny apertures 19 in the flow stream relative to the second, or drainage, end 22 of the tube 18 creates a venturi. As is generally known in the
25 relevant arts, a venturi operates through the Bernoulli effect to create a relative low pressure in areas of increased fluid flow rate in a closed or semi-closed system. According to the

present invention, the drainage end 22 of the tube 18 is connected to fluid collection canister 23 wherein the local pressure is controlled to ensure establishment of the desired venturi. In this manner, a localized suction is created at the wound site 11, notwithstanding the fact that the pressure at the wound 11 will be greater than that of the surrounding atmosphere, 5 whereby wound exudate may be safely drawn from the wound 11. This helps to eliminate moisture buildup at the wound site 11 and reduces bacterial density, thereby aiding in the control of infection and assisting in the control of edema.

As an additional benefit, the system of the present invention eliminates the need for many of the more expensive elements of infection control. For example, because the 10 collection canister 23 is at the terminal end of the pressure delivery apparatus, the requirements for hydrophobic filtering and strict contamination monitoring are reduced or eliminated. This makes the apparatus of the present invention available at far more economical rates, while maintaining patient safety standards intact.

While the foregoing description is exemplary of the preferred embodiment of the 15 present invention, those of ordinary skill in the relevant arts will recognize the many variations, alterations, modifications, substitutions and the like as are readily possible, especially in light of this description and the accompanying drawings and claims drawn hereto. In any case, because the scope of the present invention is much broader than any particular embodiment, the foregoing detailed description should not be construed as a 20 limitation of the scope of the present invention, which is limited only by the claims that may be drawn hereto.

INDUSTRIAL APPLICABILITY:

The present invention is applicable to the art of wound healing.

CLAIMS:

What is claimed is:

1. An apparatus for the promotion of wound closure, said apparatus comprising:
 - 5 a pad adapted for insertion substantially within a wound cavity;
 - a source of fluid flow;
 - a reservoir adapted for collection of wound fluids; and
 - a fluid conduit adapted for conveying said fluid flow from said source, through said pad and to said reservoir, said fluid conduit being further adapted to draw wound fluids from
 - 10 adjacent said pad into said fluid flow and away from the wound cavity.
2. The apparatus as recited in claim 1, wherein said adaptation to draw wound fluids comprises an implementation of Bernoulli's theorem.
- 15 3. The apparatus as recited in any of the preceding claims, wherein said fluid conduit comprises a hose.
4. The apparatus as recited in any of claims 2 or 3, wherein said implementation comprises the provision of a plurality of apertures in said fluid conduit, said apertures being
20 enveloped within said pad.
5. The apparatus as recited in any of the preceding claims, wherein said fluid source is adapted for the introduction to said fluid flow of a pharmaceutical product.

6. The apparatus as recited in any of the preceding claims, wherein said fluid source is adapted for the influence, through said fluid conduit, of the atmospheric condition in the region of the wound cavity.

5 7. The apparatus as recited in claim 6, wherein said influence comprises effecting atmospheric content.

8. The apparatus as recited in any of claims 6 or 7, wherein said influence comprises effecting temperature.

10

9. The apparatus as recited in any of the preceding claims, wherein said reservoir comprises a canister.

10. A method for the promotion of wound closure, said method comprising the steps of:

15 inserting a pad substantially within a wound cavity;
 providing a source of fluid flow;
 providing a reservoir adapted for collection of wound fluids; and
 conveying said fluid flow through a fluid conduit from said source, through said pad
and to said reservoir, said fluid conduit being adapted to draw wound fluids from adjacent
20 said pad into said fluid flow and away from the wound cavity.

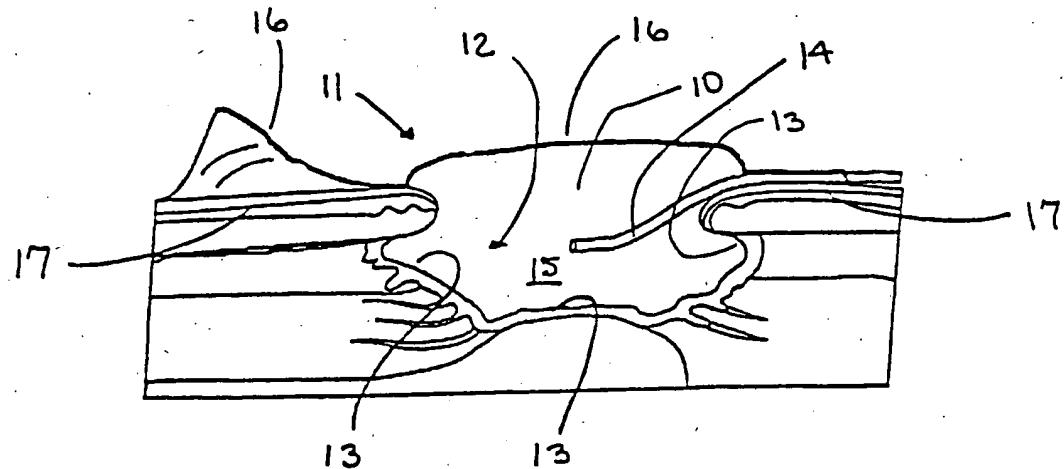


FIGURE 1

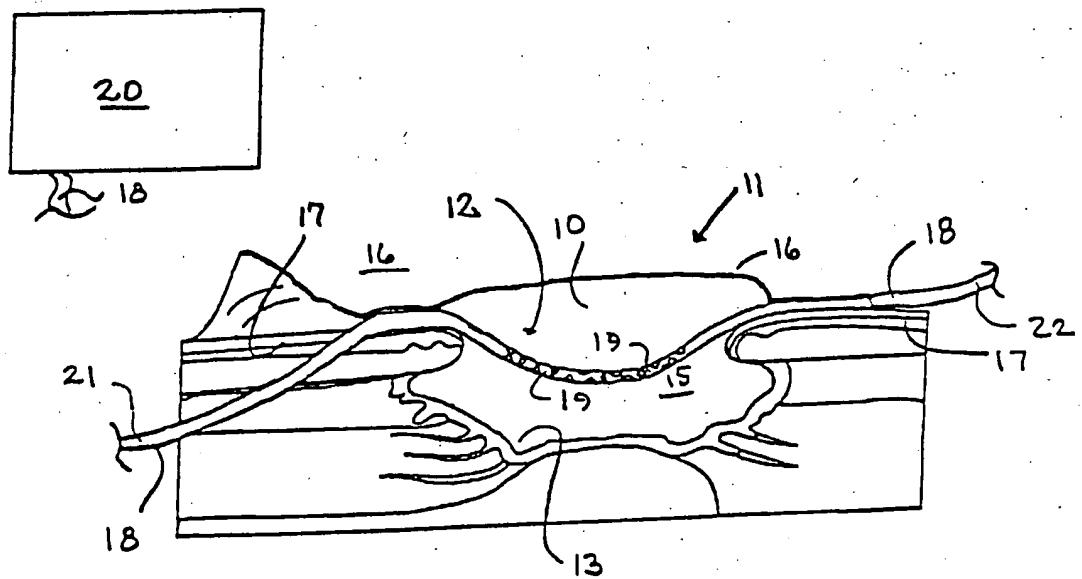


FIGURE 2.

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

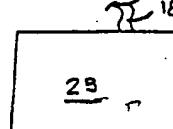
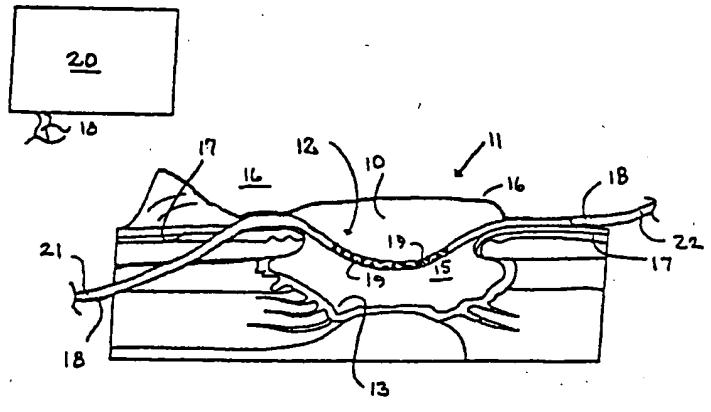


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61M 35/00	A3	(11) International Publication Number: WO 00/38755 (43) International Publication Date: 6 July 2000 (06.07.00)
--	----	---

(21) International Application Number: PCT/US99/30702 (22) International Filing Date: 23 December 1999 (23.12.99) (30) Priority Data: 60/113,732 23 December 1998 (23.12.98) US (71) Applicant (for all designated States except US): KCI LICENSING, INC. [US/US]; 8023 Vantage Drive, San Antonio, TX 78230 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): RANDOLPH, L., Tab [US/US]; 27917 Bonn Mountain, San Antonio, TX 78260 (US). (74) Agents: COLTON, Wayne, J.; Wayne J. Colton, Inc., The Milam Building, Suite 1108, 115 East Travis Street, San Antonio, TX 78205 (US) et al.	(81) Designated States: AU, CA, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report. (88) Date of publication of the international search report: 23 November 2000 (23.11.00)
--	--

(54) Title: METHOD AND APPARATUS FOR WOUND TREATMENT



(57) Abstract

A wound treatment device comprises a polyurethane or polyether foam pad (10), adapted for insertion substantially within a wound cavity; a pump (20) for supplying fluid flow to the wound site, and a collection canister (23) for receiving wound fluids drawn from the wound cavity. The foam pad (10), pump (20), and collection canister (23) are in fluid communication with one another through a single hospital grade hose (14) having a plurality of tiny apertures (19) in the portion that is central to the foam pad. These apertures (19) are adapted to allow fluids from the wound cavity to be drawn into the flow from the pump (20) to the canister (23) according to Bernoulli's theorem.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Larvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LJ	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/30702

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61M 35/00

US CL :604/290

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/28, 35, 290

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 1,114,268 A (KELLS) 20 OCT 1914, Fig.2 and related text.	1,3-7, 9, 10
Y	US 4,421,505 A (SCHWARTZ) 20 DEC 1983, Figs 1-3 and related text.	1-10
Y	US 5,636,643 A (ARGENTA et al.) 10 JUN 1997, Fig. 1 and related text.	1-10

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
---	--

Date of the actual completion of the international search

15 AUGUST 2000

Date of mailing of the international search report

18 SEP 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

MICHAEL J. HAYES

Telephone No. (703) 305-5873

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.